

REMARKS

Claims 1-53 are pending in the instant application. The Examiner has withdrawn Claims 29-53 and has rejected Claims 1-28. Applicants expressly reserve the right to file divisional applications to the subject matter not currently being pursued.

Section 102(b)

The Examiner has rejected Claims 1 and 24 under 35 USC 102(b) as allegedly being anticipated by Bilodeau et al., WO 01/17995.

Applicants respectfully traverse this rejection. For a single reference to anticipate an invention, the reference must, either expressly or inherently, disclose each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Sys., Inc.*, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984). The Examiner appears to be stating that Bilodeau et al “teaches the exact compound” and therefore allegedly anticipates Claims 1 and 24. However, the compound the Examiner refers to on page 111-112 is a free base of 4-({2-[(5-cyano-thiazol-2-yl)amino]-4-pyridinyl} methyl)-N,N-dimethyl-1-piperazinecarboxamide. Applicants respectfully point out that the compound claimed in the instant application is *not* a dimethyl compound and is not a free base form. Because each and every element is not disclosed in the cited references, Applicants assert that the references do not anticipate the claimed invention. Therefore, Applicants respectfully request that this rejection be withdrawn.

Section 103

The Examiner has rejected Claims 2-23 and 25-28 under 35 USC 103(a) as allegedly being unpatentable over Bilodeau et al.

Applicants respectfully traverse this rejection. According to section 2141 of the M.P.E.P., the "following tenets of patent law must be adhered to [when determining if an invention is obvious]:

- A) The claimed invention must be considered as a whole;
- B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention, and


D) Reasonable expectation of success is the standard with which obviousness is determined." (citations omitted)

Applicants respectfully contend that the invention, *as a whole*, is non-obviousness because the reference cited by the Examiner does not teach or suggest the instant invention. Additionally, Applicants respectfully assert that the Examiner is using an "obvious-to-try" theory to allege that the instant invention is obvious and would have had a reasonable expectation of success.

Applicants contend that the specific salt forms of the specific compound, 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide, claimed in the instant application are not taught or suggested in the Bilodeau reference. Additionally, Applicants assert that these salt forms have an unexpected advantage. As stated in *In re Mayne*, (104 F.3d 1339, CAFC 1997), the courts have "recognized that unexpected properties can show that a claimed compound that appeared to be obvious on structural grounds was not obvious when looked at as a whole." Applicants noted on page 4 and 17, the instant invention fills the need for "active, soluble salts" that can be readily administered. On page 17, it is stated that "Based on pharmacokinetic studies in animals, the presently claimed salts have an unexpectedly superior oral activity profile compared to the corresponding free base and are therefore particularly suited for oral administration." Applicants contend that the instant invention, the specific salt forms of 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide, have an unexpected property over the corresponding free base and that one with ordinary skill in the art would not have been able to predict that these salts would have superior oral activity. Therefore, Applicants contend that the reference does not render the instant invention obvious and respectfully request that this rejection be withdrawn.

Applicants respectfully contend that Claims 1-28 are allowable and an early Notice of Allowance is earnestly solicited. If a telephonic communication will aid in the advancement of the prosecution of this application, please telephone the representative indicated below.

Respectfully submitted,

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